

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA

v.

LAUREN STEVENS,

Defendant

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\* CRIMINAL NO. RWT-10-0694

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\* FILED UNDER SEAL

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**UNITED STATES' SEALED REDACTED OPPOSITION TO DEFENDANT'S MOTION  
FOR DISCLOSURE OF GRAND JURY TRANSCRIPTS**

The United States respectfully opposes defendant Lauren Stevens' motion for disclosure of the government's presentation to the grand jury relating to the advice of counsel defense and 18 U.S.C. § 1515(c). The United States asks the Court to allow this opposition to be filed under seal,<sup>1</sup> pursuant to Federal Rule of Criminal Procedure 6(e). Together with this redacted opposition that is being served on the defendant, the government is filing (also under seal) an *ex parte* opposition.

The government did not abuse the grand jury process. Nothing submitted by the defendant supports such a suggestion or provides any other ground sufficient to rebut the presumption of regularity that protects grand jury proceedings. Federal Rule of Criminal Procedure 6(e)(3)(E)(ii) sets forth the only basis for the Court to grant Stevens' motion: it provides that the Court may authorize disclosure of a grand jury matter "at the request of a defendant who shows that a ground may exist to dismiss the indictment because of a matter that occurred before the grand jury." No such ground exists here, nor has Stevens come close to

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<sup>1</sup> The government is filing with this opposition a separate motion to seal.

showing that such a ground may exist. Only a defendant who has demonstrated with particularity that there is a compelling necessity to disclose grand jury transcripts is entitled to receive such materials, and Stevens has failed to meet her burden. The premise of her argument – that the United States withheld exculpatory evidence from the grand jury – is legally flawed. The government is not required to present exculpatory evidence to the grand jury. *See United States v. Williams*, 504 U.S. 36, 51-55 (1992).

**I. Background**

Promoting drugs for unapproved uses constitutes the distribution and introduction into interstate commerce of misbranded drugs in violation of the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301, *et seq.*. In October 2002, the FDA sent GSK a letter stating that the FDA had become aware of information suggesting that GSK was promoting Wellbutrin for weight loss. Because Wellbutrin had been approved only for the treatment of depression in adults, weight loss was an off-label use of the drug. The FDA asked GSK to provide it with materials related to GSK’s Wellbutrin promotional programs, including copies of all slides, videos, handouts, and other materials.

Stevens was in charge of GSK’s response to the FDA. Stevens headed a team of lawyers and paralegals from GSK and from an outside law firm – King & Spalding – that GSK hired to assist the company in its response. In response to the FDA’s inquiry, Stevens signed a series of letters from GSK to the FDA. Those letters are the basis of the four false statement charges in the indictment (Counts Three through Six). The letters are also the basis, together with materials that Stevens did not provide to the FDA, for the two obstruction charges (Counts One and Two). Stevens’ notes and other evidence demonstrate that Stevens was, among other things, trying to

avoid or minimize any regulatory action by the FDA against GSK in connection with the company's promotion of Wellbutrin, attempting to prevent the use of the evidence in potential future investigations, and trying to stop the investigation from expanding into other drugs.

**II. Stevens Has Not and Cannot Demonstrate the Required Particularized Need for Disclosure of Grand Jury Materials**

A. A Defendant Must Demonstrate a Particularized Need for Grand Jury Materials to be Disclosed

Stevens has not established any basis for dismissing the indictment based upon what occurred before the grand jury, nor has she shown that she has the particularized need necessary to justify the grand jury disclosures she seeks. Under Federal Rule of Criminal Procedure 6(e)(3)(E)(ii), a court may authorize the disclosure of grand jury matters "at the request of a defendant who shows that a ground may exist to dismiss the indictment because of a matter that occurred before the grand jury." The Supreme Court has said that a long-established policy maintains the secrecy of grand jury proceedings. *United States v. Proctor & Gamble Co.*, 356 U.S. 677, 681-82 (1958). This secrecy may not be broken, the Court has said, "except where there is a compelling necessity." *Id.* at 682. The Court has recognized that there are instances where the need for disclosure outweighs the public interest in secrecy, but has stated that such instances "must be shown with particularity." *Id.* See also *United States v. Sells Eng'g, Inc.*, 463 U.S. 418, 443 (1983); *Douglas Oil Co. of Cal. v. Petrol Stops Northwest*, 441 U.S. 211, 221-22 (1979). The party seeking disclosure bears the burden of demonstrating a particularized need for disclosure of the grand jury materials. *See In re Grand Jury Proceedings*, 800 F.2d 1293, 1299 (4th Cir. 1986).

The same "particularized need" standard the Supreme Court has articulated for third

parties seeking the disclosure of grand jury matters under Fed. R. Crim. P. 6(e)(3)(E)(i) also governs requests for grand jury materials from defendants under Rule 6(e)(3)(E)(ii). *See, e.g.*, *United States v. Miner*d, 299 F. App'x 110, 111 (3d Cir. 2008) (unpublished) (vague allegation does not demonstrate a particularized need for disclosure); *United States v. Broyles*, 37 F.3d 1314, 1318 (8th Cir. 1994) (“A long line of cases in this Circuit note that ‘a bare allegation that the records [of a grand jury] are necessary to determine if there may be a defect in the grand jury process does not satisfy the ‘particularized need’ requirement.’”); *United States v. Puglia*, 8 F.3d 478, 480 (7th Cir. 1993); *United States v. Walczak*, 783 F.2d 852, 857 (9th Cir. 1986); *United States v. Nguyen*, 314 F.Supp.2d 612, 616 (E.D. Va. 2004) (collecting cases).

Moreover, grand jury proceedings enjoy a presumption of regularity. *Hamlin v. United States*, 418 U.S. 87, 139 n.23 (1974). Rule 6(e)(3)(E)(ii) “is not an invitation to engage in a fishing expedition to search for grand jury wrongdoing and abuse when there are no grounds to believe that any wrongdoing or abuse has occurred.” *Nguyen*, 314 F. Supp. 2d at 616. As the district court in *Nguyen* noted, “a defendant seeking disclosure of grand jury information under Rule 6(e)(3)(E)(ii) bears the heavy burden of establishing that ‘particularized and factually based grounds exist to support the proposition that irregularities in the grand jury proceedings may create a basis for dismissal of the indictment.’” *Id.* (citations omitted); *see United States v. Harris*, 2007 WL 1724298, at \*5 (N.D.W.V. 2007) (noting that a defendant seeking disclosure of testimony before the grand jury that indicted him, must demonstrate that irregularities or misconduct in the grand jury proceedings may create a basis for dismissing the indictment). Due to the heavy burden facing a defendant, disclosure of grand jury testimony “will be denied in all but extraordinary circumstances.” *United States v. Morgan*, 845 F. Supp. 934, 941 (D. Conn.

1994) (noting that the strong presumption of regularity in grand jury proceedings cannot be outweighed by conclusory or speculative allegations of misconduct). Stevens has not shown that her case presents any extraordinary circumstances.

Moreover, although at this point Stevens is asking only for disclosure of the grand jury transcripts and has not yet moved to dismiss the indictment, it is important to note that the burden a defendant must meet to dismiss an indictment is heavy. The dismissal of an indictment based on prosecutorial misconduct is appropriate only if the violation substantially influenced the grand jury's decision to indict or if there is "grave doubt" that the decision to indict was free from prejudice. *Bank of Nova Scotia v. United States*, 487 U.S. 250, 256 (1988). An indictment that is valid on its face "is not subject to challenge on the ground that the grand jury acted on the basis of inadequate or incompetent evidence." *United States v. Calandra*, 414 U.S. 338, 345 (1974). The mere fact that evidence is unreliable is not sufficient to require dismissal of the indictment. *Costello v. United States*, 350 U.S. 359, 363 (1956). Nothing offered by Stevens meets this standard.

B. The Government Need Not Present Exculpatory Evidence to the Grand Jury

1. The Supreme Court Has Expressly Held that the Government Has No Obligation to Present Exculpatory Evidence to the Grand Jury

The government need not present exculpatory evidence to the grand jury. The Supreme Court made this clear in *United States v. Williams*, 504 U.S. 36 (1992), a case cited by Stevens in a footnote on page 11 of her memorandum. The Supreme Court stated:

Requiring the prosecutor to present exculpatory as well as inculpatory evidence would alter the grand jury's historical role, transforming it from an accusatory to an adjudicatory body. It is axiomatic that the grand jury sits not to determine guilt or innocence, but to assess whether there is adequate basis for bringing a criminal

charge. That has always been so; and to make the assessment it has always been thought sufficient to hear only the prosecutor's side. . . . Imposing upon the prosecutor a legal obligation to present exculpatory evidence in his possession would be incompatible with this system. If a "balanced" assessment of the entire matter is the objective, surely the first thing to be done – rather than requiring the prosecutor to say what he knows in defense of the target of the investigation – is to entitle the target to tender his own defense. To require the former while denying (as we do) the latter would be quite absurd.

*Id.* at 51-52 (citations omitted). *See also United States v. McDonald*, 61 F.3d 248, 253 (4th Cir. 1995) ("a prosecutor is under no obligation to produce even substantially exculpatory evidence"); *United States v. James*, 2010 WL 4053571, at \*4 (S.D. Ohio 2010) ("Defendant cannot break the seal of silence of the grand jury proceedings on the basis of an assertion that the Government did not produce exculpatory material to the grand jury"); *United States v. Olin Corp.*, 465 F. Supp. 1120, 1128 (W.D.N.Y. 1979) ("The prosecutor does not have a duty to present defendant's version of the facts.").

## 2. The Cases Cited by Stevens Are Not Persuasive

Despite the clarity of the law on this point, Stevens' motion suggests that if the government did not instruct or present evidence to the grand jury about her purported advice of counsel defense, the indictment must be dismissed. *Def. Memo.* at 10-11. However, the cases Stevens cites do not support this proposition, nor do they undermine the Supreme Court's holding in *Williams* that exculpatory evidence need not be presented to the grand jury.

In *McDonald*, cited on pages 10-11 of Stevens' memo, the Fourth Circuit refused after conviction to quash an indictment returned by a grand jury that heard testimony from an agent who improperly referred to polygraph tests and improperly left the impression that witnesses against the defendant had passed polygraph tests. 61 F.3d at 252-53. The Fourth Circuit stated

that an indictment may be quashed on the basis of prosecutorial misconduct only where the government's misdeeds "substantially influenced the grand jury's decision to indict," or if there is 'grave doubt' that the decision to indict was free from the substantial influence of such violations." *Id.* at 253 (citations omitted). The *McDonald* court went on to say that *Williams* "made clear that a failure by the government to disclose even substantial exculpatory evidence to the grand jury does not constitute such misconduct." *Id.*

In *United States v. Lawson*, 502 F. Supp. 158 (D. Md. 1980), cited by Stevens on page 11, the defendant argued that "the prosecutor's conduct was not simply a matter of failing to present known, exculpatory evidence to the grand jury," but rather was "an affirmative attempt . . . to turn exculpatory evidence into inculpatory evidence." 502 F. Supp. at 162. The district court dismissed the indictment without prejudice, finding that the defendant's right to an unbiased grand jury had been denied when the prosecutor asked misleading questions and failed to disclose known, exculpatory evidence. *Id.* at 172.

In *United States v. Twersky*, 1994 WL 319367 (S.D.N.Y. 1994), cited by Stevens on page 11, the district court agreed to review grand jury minutes *in camera* to see whether the legal instructions given to the grand jury were rendered faulty in light of a Supreme Court decision changing the law that was issued after the indictment was returned. The district court said in dicta that "an indictment will be dismissed where, for instance, the evidence clearly establishes a defense to the charge and the government fails to inform the grand jury of the legal requirements of the defense." *Id.* at \*4. Even though it was decided after *Williams*, *Twersky* cited two pre-*Williams* state court decisions in support of this statement.

Stevens cites *United States v. Walters*, 333 F. Supp. 2d 1022, 1032 (D. Kan. 2004), in

support of the proposition that Stevens would have been seriously prejudiced if evidence of an affirmative defense obtained in testimony in Massachusetts was not presented to the grand jury in Maryland. *Def. Memo.* at 11. The district court in *Walters*, however, relied on *United States v. Page*, 808 F.2d 723, 737 (10th Cir. 1987), which required the government to present substantial exculpatory evidence. *Page* was decided before the Supreme Court held in *Williams* that the government was not required to present exculpatory evidence. (It should be noted that neither *Page* nor *Walters* found the alleged government misconduct sufficient to overturn the convictions.)<sup>2</sup>

Stevens also points to the United States Attorneys' Manual § 9-11.233, which states:

In *United States v. Williams*, 112 S.Ct. 1735 (1992), the Supreme Court held that the Federal courts' supervisory powers over the grand jury did not include the power to make a rule allowing the dismissal of an otherwise valid indictment where the prosecutor failed to introduce substantial exculpatory evidence to a grand jury. It is the policy of the Department of Justice, however, that when a prosecutor conducting a grand jury inquiry is personally aware of substantial evidence that directly negates the guilt of a subject of the investigation, the prosecutor must present or otherwise disclose such evidence to the grand jury before seeking an indictment against such a person. While a failure to follow the Department's policy should not result in dismissal of an indictment, appellate courts may refer violations of the policy to the Office of Professional Responsibility for review.

United States Attorney's Manual § 9-11.233. Even if the government had not followed the

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<sup>2</sup> The remaining cases Stevens cites on page 12 of her memorandum are also distinguishable. In *United States v. McGowan*, 423 F.3d 413, 418 (4th Cir. 1970), the court found that the district court should have given the defendant access to the grand jury testimony of two witnesses who testified at trial for the government. In *United States v. Peralta*, 763 F. Supp. 14, 19-20 (S.D.N.Y. 1991), the district court dismissed an indictment where the government misled the grand jury about the law. The district court in *United States v. Breslin*, 916 F. Supp. 438 (E.D. Pa. 1996), dismissed an indictment after a host of grand jury improprieties, including the prosecutor providing the grand jury with snacks, suggesting that live testimony was not possible, and saying that he had limited time to present the case.

Department's policy, the Court would not have grounds to dismiss the indictment. *Cf. United States v. Serrano*, 406 F.3d 1208, 1218 (10th Cir. 2005) (holding that *United States Attorneys' Manual* does not create any substantive or procedural rights); *United States v. Fernandez*, 231 F.3d 1240, 1246 (9th Cir. 2000) (same). Moreover, the United States did not act contrary to its own policies here, because the advice of counsel defense does not negate Stevens' guilt.

3. Williams Is Decisive

The government had no obligation to present Stevens' defense to the grand jury. A grand jury proceeding is not a trial. *See Calandra*, 414 U.S. at 343-43 ("The grand jury proceeding is not an adversary hearing in which the guilt or innocence of the accused is adjudicated."); *United States v. Gardner*, 860 F.2d 1391, 1395 (7th Cir. 1988) (a defendant "is entitled to one criminal trial, not two").

The *Williams* ruling should end the Court's inquiry. Rule 6(e)(3)(E)(ii) authorizes disclosing grand jury materials to the defendant only if the defendant shows that a ground may exist to dismiss the indictment because of a matter that occurred before the grand jury. Because, under *Williams*, the failure to present exculpatory evidence to the grand jury is not a ground for dismissing the indictment, Stevens has not established that there is a ground for dismissal, as required by Rule 6(e)(3)(E)(ii).

C. There Was No Exculpatory Evidence for the Government to Present

1. Stevens Does Not Have an Advice of Counsel Defense

Advice of counsel is not a defense to the 18 U.S.C. § 1519 charge. As the government has briefed in its pending motion to exclude the advice of counsel defense (DE 19), this statute prohibits "knowingly" concealing, covering up, or falsifying any record "with the intent to

impede, obstruct, or influence" a matter within the jurisdiction of a federal agency. Acting with the intent to obstruct in violation of 18 U.S.C. § 1519 is a general intent crime that requires proof the defendant was acting voluntarily, as opposed to proof the defendant knew her conduct was illegal. Advice of counsel is not a defense to crimes that do not require specific intent.

Stevens does not have a valid advice of counsel defense with respect to the four counts charging her with violating 18 U.S.C. § 1001 and the one count charging her with violating 18 U.S.C. § 1512. That Stevens worked with other lawyers in responding to the FDA's inquiry does not an advice of counsel defense make. Consulting with an attorney does not insulate a defendant from criminal liability for conduct the defendant knows is wrong. The advice of counsel defense requires the defendant to prove that she relied in good faith on counsel's advice. Stevens knew her letters to the FDA were false; thus she cannot reasonably have relied upon any such claimed advice in order to make false statements and obstruct the investigation. It cannot be reasonable for someone to rely upon an attorney to advise her to knowingly make false statements. This is particularly true when the person claiming to be advised is an attorney herself, and an attorney who had dealt with the FDA before in the highly regulated pharmaceutical environment.

The advice of counsel defense also requires the defendant to prove that she fully disclosed all pertinent facts to her attorney. *See e.g.*, L. Sand, *et al.*, *Modern Federal Jury Instructions: Criminal Pattern Instruction* § 8.04 (Reliance on Counsel) (requiring that defendant "fully and honestly laid all the facts before his lawyer"). The scope of King & Spalding's assignment was narrow. The evidence will show that Stevens did not fully disclose all relevant facts to the King & Spalding lawyers, nor did she seek advice from them on all of the issues.

2. Advice of Counsel Is an Affirmative Defense That Need Not Be Presented to the Grand Jury

Even if Stevens had a legitimate advice of counsel defense – an issue that will ultimately be resolved by the Court on the law and/or by the petit jury on the facts – such a defense does not directly negate guilt. Advice of counsel is an affirmative defense; it is not exculpatory evidence and it does not directly negate guilt. An affirmative defense such as advice of counsel need not be presented to the grand jury. *See People of the Territory of Guam v. Cruz*, 913 F.2d 748, 750 (9th Cir. 1990) (government not required to instruct grand jury on affirmative defense of self-defense); *Gardner*, 860 F.2d at 1395 (affirming district court's ruling that affirmative defenses did not negate guilt and evidence of such need not be presented to the grand jury); *United States v. Gavran*, 620 F. Supp. 1277, 1281 (E.D. Wis. 1985) (advice of counsel an affirmative defense to be raised at trial, not exculpatory evidence clearly negating guilt that must be presented to the grand jury); *United States v. DePalma*, 461 F.Supp. 778, 797 (S.D.N.Y. 1978) (affirmative defense of entrapment did not directly negate the charge and need not have been presented to the grand jury).

3. Providing Lawful Legal Representation Is an Affirmative Defense That Need Not Be Presented to the Grand Jury

Stevens argues that, along with her advice of counsel defense, she also has a defense to the obstruction charges under 18 U.S.C. § 1515(c). *Def. Memo.* at 10. Section 1515(c) states: "This chapter does not prohibit or punish the providing of lawful, bona fide, legal representation services in connection with or anticipation of an official proceeding." This statute constitutes an affirmative defense, not an element of the crime. *See United States v. Kloess*, 251 F.3d 941, 946, 949 (11th Cir. 2001). As discussed above, the government is not required to present affirmative

defenses to the grand jury. Knowingly acting corruptly is antithetical to providing lawful, bona fide, legal representation. The prototypical situation protected by § 1515(c) is where an attorney advises a client not to reveal information to law enforcement officials. *See United States v. Farrell*, 126 F.3d 484, 488 (3d Cir. 1997). Stevens is not charged with advising GSK not to respond to the FDA's inquiry; rather, she is charged with responding to the FDA's inquiry in a misleading and obstructionist manner. Section 1515(c) provides a safe harbor only to individuals who are providing "lawful" legal representation. To the extent Stevens was providing legal representation to GSK, as opposed to acting as its agent in responding to the FDA, Stevens was not providing lawful representation when she knowingly made false statements and engaged in obstruction.

Stevens has not met her burden of establishing that she has a particularized need for the release of the grand jury transcripts.

III. Conclusion

Accordingly, the government respectfully submits that the defendant has offered no basis to suggest that the government has acted improperly or to pierce the secrecy of the grand jury proceedings here and requests that the Court deny the defendant's motion.

Dated: December 21, 2010

Respectfully submitted,

TONY WEST  
Assistant Attorney General  
U.S. Department of Justice

SARA MIRON BLOOM  
Assistant United States Attorney  
United States Courthouse  
Suite 9200  
1 Courthouse Way  
Boston, MA 02210  
(617)748-3265

/s/  
PATRICK JASPERSE  
Trial Attorney  
U.S. Department of Justice  
Office of Consumer Litigation  
P.O. Box 386  
Washington, DC 20044  
(202) 616-0509

CERTIFICATE OF SERVICE

I hereby certify that on December 21, 2010, a copy of the foregoing United States' Sealed Redacted Opposition to Defendant's Motion for Disclosure of Grand Jury Transcripts was served via electronic mail upon the following defense counsel:

Reid H. Weingarten  
William T. Hassler  
Robert Ayers  
Steptoe and Johnson LLP  
1330 Connecticut Ave., NW  
Washington, DC 20036  
[Rweingarten@steptoe.com](mailto:Rweingarten@steptoe.com); [whassler@steptoe.com](mailto:whassler@steptoe.com); [rayers@steptoe.com](mailto:rayers@steptoe.com)

Michelle L. Levin  
Steptoe and Johnson LLP  
750 Seventh Ave.  
New York, NY 10019  
[millevin@steptoe.com](mailto:millevin@steptoe.com)

Brien T. O'Connor  
Ropes and Gray LLP  
Prudential Tower  
800 Boylston St.  
Boston, MA 02199  
[Brien.O'Connor@ropesgray.com](mailto:Brien.O'Connor@ropesgray.com)

Colleen A. Conry  
Ropes and Gray LLP  
700 12th St., NW, Suite 900  
Washington, DC 20005  
[Colleen.Conry@ropesgray.com](mailto:Colleen.Conry@ropesgray.com)

/s/  
Patrick Jisperse  
Trial Attorney  
U.S. Department of Justice  
Office of Consumer Litigation  
P.O. Box 386  
Washington, DC 20044  
(202) 616-0509